K023878

JAN 2 4 2003

Section 6
Summary of Safety and Effectiveness

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Pursuant to Section 12, Safe Medical Devices Act of 1990)

1. **Identifying Information:**

1.1. **Submitters Name:** Medtronic AVE, Inc.
37A Cherry Hill Drive
Danvers, MA 01923

1.2. **Contact Person:** Fred L. Boucher R.A.C.
(978) 777-0042

2. **Classification Name:** Device, Coronary Saphenous Vein Graft, Temporary, for Embolization Protection (21 CFR Part 870.1250)

3. **Proprietary Name:** GuardWire Temporary Occlusion and Aspiration System

4. **Name of Predicate Devices:** GuardWire Temporary Occlusion and Aspiration System

5. **Description**:

The GuardWire Plus Temporary Occlusion & Aspiration System provides temporary vascular occlusion during diagnostic and interventional procedures in coronary saphenous bypass grafts. The system is used to contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures and is comprised of four principal components: the GuardWire Temporary Occlusion Catheter, the MicroSeal® Adapter and the Export® Aspiration Catheter and the EZ Flator Inflation Device. The GuardWire may also be used during these procedures alone or in conjunction with the Export Catheter to locally infuse diagnostic or therapeutic agents with or without vessel occlusion.

The modification to the GuardWire system addressed with this submission entails the introduction of the EZ-Adapter as a replacement for the MicroSeal Adapter (MSA), as the device that actuates the MicroSeal of the GuardWire device.

Both the EZ Adapter and the MicroSeal Adapter provide the same mechanical functions:

- hold the GuardWire in a static fixed position,
- actuate, through linear movement, the MicroSeal plug system of the GuardWire, and
- provide direct communication from the EZ Flator inflation device to the GuardWire balloon to facilitate inflation or deflation of the GuardWire balloon.

Intended-Use:

The GuardWire 3-6 Temporary Occlusion & Aspiration System is indicated for use in the coronary saphenous vein bypass grafts to:

- Contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures.
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

Technology:

The EZ Adapter is manufactured under the same conditions, using the similar processes and equivalent materials, as the MicroSeal Adapter that is contained in the GuardWire Temporary Occlusion and Aspiration System; the legally marketed predicate device. In addition to being technologically equivalent, the indications for use have not changed.

The EZ Adapter has been subjected to performance testing and it has been determined that the EZ Adapter is substantially equivalent to the MicroSeal Adapter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2003

Mr. Fred L. Boucher, R.A.C.
Sr. Regulatory Affairs Manager
Medtronic AVE
37A Cherry Hill Drive
Danvers, MA 01923

Re: K023878
Trade/Device Name: GuardWire 3-6 Temporary Occlusion and Aspiration System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NFA
Dated: December 24, 2002
Received: December 26, 2002

Dear Mr. Boucher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

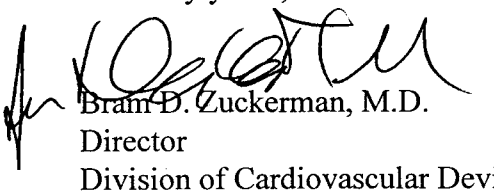
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K023878

Device Name: GuardWire Temporary Occlusion and aspiration System

Indications for Use:

The GuardWire 3-6 Temporary Occlusion & Aspiration System is indicated for use in the coronary saphenous vein bypass grafts to:

- Contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures.
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023878